

General

Guideline Title

Consensus guidelines for periprocedural management of coagulation status and hemostasis risk in percutaneous image-guided interventions.

Bibliographic Source(s)

Patel IJ, Davidson JC, Nikolic B, Salazar GM, Schwartzberg MS, Walker TG, Saad WA, Standards of Practice Committee, Cardiovascular and Interventional Radiological Society of Europe (CIRSE) Endorsement. Consensus guidelines for periprocedural management of coagulation status and hemostasis risk in percutaneous image-guided interventions. *J Vasc Interv Radiol*. 2012 Jun;23(6):727-36. [89 references] [PubMed](#)

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Malloy PC, Grassi CJ, Kundu S, Gervais DA, Miller DL, Osnis RB, Postoak DW, Rajan DK, Sacks D, Schwartzberg MS, Zuckerman DA, Cardella JF, Standards of Practice Committee with Cardiovascular and Interventional [trunc]. Consensus guidelines for periprocedural management of coagulation status and hemostasis risk in percutaneous image-guided interventions. *J Vasc Interv Radiol*. 2009 Jul;20(7 Suppl):S240-9. [56 references]

Recommendations

Major Recommendations

Recommendations for Preprocedure Testing and Management

Assessment and preparation of the patient before image-guided procedures will vary according to the procedure to be performed in conjunction with a comprehensive assessment of the patient's comorbidities. Although image guidance is likely to make minimally invasive procedures more accurate, for example, in their ability to target lesions or to put effector devices such as needles or catheters in optimal position, by their very nature, these procedures preclude the operator from direct visualization of postprocedural bleeding. The lack of available randomized, controlled studies specific to image-guided percutaneous procedures has resulted in considerable variety in clinical practice. In addition, it is doubtful that one can extrapolate the results from open surgical procedures to minimally invasive procedures because of the aforementioned separation of the operator from direct assessment of bleeding (and the associated ability to control it) at the site of the procedure.

Recommendations for patient evaluation and general indications for the use of blood products and other hemostatic agents are outlined in the tables below. Where reliable data were lacking, recommendations were derived by Delphi consensus of a panel of expert practitioners. The tables represent the results of the Delphi consensus panel, which were derived for the management of a patient with a single hemostatic defect. A total of 18 Certificate of Added Qualification–certified interventional radiologists participated in a four-round Delphi process. Although representative procedures were placed into one of three categories of risk, as outlined in the tables below, the panel believed there was significant potential variability in risk from procedure to procedure within each category, depending on the individual patient comorbidities and possible multiple

concomitant hemostatic defects. It must be stressed, therefore, that specific assessment of bleeding risk and considerations for the use of blood products or other hemostatic agents must be individualized to the patient at the total discretion of the performing physician, who must, at the time of the procedure, make clinical decisions based on an often complex array of patient variables, comorbidities, and concomitant hemostatic defects. With respect to the categories in the tables below, any individual procedure might possibly be treated at a higher risk level, depending on these individual patient factors. In addition, for the purposes of this document, the Delphi consensus panel treated the procedures as elective, with a single hemostatic defect. Emergency indications, multiple concomitant hemostatic defects, and the use of topical or intravascular/perivascular closure devices were not specifically addressed. Numerous maneuvers and modifications, such as needle tract embolization, have been employed to potentially reduce bleeding risks; however, there is no concrete evidence-based research showing their added efficacy, and therefore they will not be further delineated. Emergency or highly urgent procedures, in which the risk of procedural delay may outweigh the potential hemorrhagic risk, may not afford the time for equivalent correction of hemostatic defects as may be achieved in elective procedures. The physician must take into account pathophysiologic, psychosocial, medicolegal, and religious variables in coming to an overall assessment of the patient. For example, periprocedural management for percutaneous liver biopsy may vary significantly between one patient with an international normalized ratio (INR) of 1.7 with no comorbidities and a second patient with INR of 1.7 and concomitant renal failure and cirrhosis.

As there is no evidence to support the use of bleeding times before minimally invasive procedures, the Delphi consensus panel did not address the use of this test. In addition, the use of recombinant factor VIIa was not addressed. Nonsteroidal anti-inflammatory drug (NSAID) use was not specifically addressed by the panel. Although NSAIDs can inhibit platelet function, the effect is reversible with clearance of the drug. Furthermore, NSAIDs tend to cause bleeding mostly in patients with preexisting coagulopathies. Low-molecular-weight heparin (LMWH) was considered by the panel with respect to therapeutic dosing.

Category 1: Procedures with Low Risk of Bleeding, Easily Detected and Controllable		
Procedures	Preprocedure Laboratory Testing	Management
Vascular: <ul style="list-style-type: none"> • Dialysis access interventions • Venography • Central line removal • IVC filter placement • PICC line placement Nonvascular: <ul style="list-style-type: none"> • Drainage catheter exchange (biliary, nephrostomy, abscess catheter) • Thoracentesis • Paracentesis • Superficial aspiration and biopsy (excludes intrathoracic or intraabdominal sites): thyroid, superficial lymph node • Superficial abscess drainage 	<ul style="list-style-type: none"> • INR: routinely recommended for patients receiving warfarin anticoagulation or with known or suspected liver disease • aPTT: routinely recommended for patients receiving intravenous unfractionated heparin • Platelet count: not routinely recommended • Hematocrit: not routinely recommended 	<ul style="list-style-type: none"> • INR >2.0: threshold for treatment (i.e., FFP, vitamin K) • PTT: no consensus • Hematocrit: no recommended threshold for transfusion • Platelets: transfusion recommended for counts <50,000/μl • Clopidogrel: withhold for 5 days before procedure • Aspirin: do not withhold • LMWH (therapeutic dose): withhold one dose before procedure
There was an 80% consensus on each of these recommendations unless stated otherwise. The management recommendations for each coagulation defect and drug assume that no other coagulation defect is present and that no other drug that might affect coagulation status has been administered. 1-Deamino-8-D-arginine vasopressin may be indicated before image-guided procedures in patients with hemophilia and von Willebrand's disease.		
Abbreviations: aPTT = activated partial thromboplastin time, FFP = fresh frozen plasma, INR = international normalized ratio, IVC = inferior vena cava, LMWH = low-molecular-weight heparin, PICC = peripherally inserted central catheter, PTT = partial thromboplastin time.		

Category 2: Procedures with Moderate Risk of Bleeding		
Procedures	Preprocedure Laboratory Testing	Management
Vascular: <ul style="list-style-type: none"> • Angiography, arterial intervention with access size up to 7 F • Venous interventions 	<ul style="list-style-type: none"> • INR: recommended • aPTT: recommended in patients receiving intravenous unfractionated heparin • Platelet count: not routinely 	<ul style="list-style-type: none"> • INR: correct to <1.5 • aPTT: no consensus (trend toward correcting for values >1.5\times control, 73% consensus) • Platelets: Transfusion recommended for

Category 2: Procedures with Moderate Risk of Bleeding		
Procedures	Preprocedure Laboratory Testing	Management
<ul style="list-style-type: none"> Chemoembolization Uterine fibroid embolization Transjugular liver biopsy Tunneled central venous catheter Subcutaneous port device <p>Nonvascular:</p> <ul style="list-style-type: none"> Intraabdominal, chest wall, or retroperitoneal abscess drainage or biopsy Lung biopsy Transabdominal liver biopsy (core needle) Percutaneous cholecystostomy Gastrostomy tube: initial placement Radiofrequency ablation: straightforward Spine procedures (vertebroplasty, kyphoplasty, lumbar puncture, epidural injection, facet block) 	<ul style="list-style-type: none"> Hematocrit: not routinely recommended 	<ul style="list-style-type: none"> Hematocrit: no recommended threshold for transfusion Clotting counts <50,000/μl Clotidogrel: withhold for 5 days before procedure Aspirin: do not withhold LMWH (therapeutic dose): Withhold one dose before procedure
Abbreviations: aPTT = activated partial thromboplastin time, INR = international normalized ratio, LMWH = low-molecular-weight heparin.		

Category 3: Procedures with Significant Bleeding Risk, Difficult to Detect or Control		
Procedures	Preprocedure Laboratory Testing	Management
<p>Vascular:</p> <ul style="list-style-type: none"> TIPS <p>Nonvascular:</p> <ul style="list-style-type: none"> Renal biopsy Biliary interventions (new tract) Nephrostomy tube placement Radiofrequency ablation: complex 	<ul style="list-style-type: none"> INR: routinely recommended aPTT: routinely recommended in patients receiving intravenous unfractionated heparin infusion. No consensus on patients not receiving heparin Platelet count: routinely recommended Hematocrit: routinely recommended 	<ul style="list-style-type: none"> INR: correct to <1.5 aPTT: stop or reverse heparin for values >1.5 times control Platelets <50,000: transfuse Hematocrit: no recommended threshold for transfusion Clotidogrel: withhold for 5 days before procedure Aspirin: withhold for 5 days Fractionated heparin: withhold for 24 hours or up to 2 doses
There was an 80% consensus on each of these recommendations unless stated otherwise. The management recommendations for each coagulation defect and drug assume that no other coagulation defect is present and that no other drug that might affect coagulation status has been administered. 1-Deamino-8-D-arginine vasopressin may be indicated before image-guided procedures in patients with hemophilia and von Willebrand's disease.		
Abbreviations: aPTT = activated partial thromboplastin time, INR = international normalized ratio, TIPS = transjugular intrahepatic portosystemic shunt.		

Summary

In the original guideline document, the guideline committee attempts to summarize some of the available literature regarding periprocedural surveillance and management of hemostatic defects in patients undergoing percutaneous image-guided procedures. Because of the lack of randomized controlled studies or other high-level evidence on this topic, a Delphi panel of experts constructed a set of consensus guidelines to hopefully serve as a reference for the practicing interventionalist in constructing their individual practice guidelines. Although it is likely that individual practice parameters will vary from this document, each practitioner should monitor outcomes and look for trends, both positive and negative, which may suggest modifications or adjustments to these parameters. Outlining bleeding complication rates for specific procedures is beyond the scope of this document and, in many cases, may be difficult or impossible to accurately accomplish because of the lack of high-level data. Where external benchmarks are not available, practitioners may choose to benchmark against their own historical data as part of an overall quality improvement program.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Coagulation abnormalities leading to bleeding complications during percutaneous image-guided interventions

Guideline Category

Evaluation

Management

Prevention

Risk Assessment

Clinical Specialty

Hematology

Internal Medicine

Preventive Medicine

Radiology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To provide recommendations for periprocedural management of coagulation status and hemostasis risk in percutaneous image-guided interventions
- To summarize some of the available literature regarding periprocedural surveillance and management of hemostatic defects in patients undergoing percutaneous image-guided procedures

Target Population

Patients with abnormal coagulation parameters undergoing percutaneous image-guided interventions

Interventions and Practices Considered

Assessment

1. Assessment of risk factors and comorbidities
2. Assessment of coagulation status using the following tests
 - International normalized ratio (INR)/prothrombin time (PT)
 - Activated partial thromboplastin time (aPTT)
 - Platelet count
 - Hematocrit

Management/Prevention

1. Management for procedures with low risk of bleeding
 - Fresh frozen plasma (FFP) and vitamin K
 - Platelet transfusion
 - Withholding clopidogrel for 5 days before procedure
 - No withholding of aspirin
 - Withholding of one therapeutic dose of low-molecular-weight heparin (LMWH) before procedure
2. Management for procedures with moderate risk of bleeding
 - Correcting INR and aPTT before procedure
 - Platelet transfusion
 - Withholding clopidogrel for 5 days before procedure
 - No withholding of aspirin
 - Withholding one therapeutic dose of LMWH before procedure
3. Management for procedures with significant bleeding risk difficult to detect or control
 - Correcting INR before procedure
 - Stopping or reversing heparin
 - Platelet transfusion
 - Withholding clopidogrel and aspirin for 5 days before procedure
 - Withholding fractionated heparin for 24 h or up to two doses

Major Outcomes Considered

Risk and incidence of bleeding during percutaneous image-guided interventions

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

An in-depth literature search was performed by using electronic medical literature databases (mainly PubMed searching from 1974 to 2012). Search terms included *minimally invasive procedure, coagulation management, anticoagulation management, periprocedural, hemostasis, Coumadin, heparin, aspirin, clopidogrel, biopsy, endovascular, bleeding risk, blood transfusion, fresh frozen plasma*.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

A critical review of peer-reviewed articles is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, complication rates, outcomes, and thresholds for prompting quality assurance reviews.

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned depending on the magnitude of the project.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members by using a modified Delphi consensus method. For the purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

Eighteen Certificate of Added Qualifications–certified members of the Society of Interventional Radiology (SIR) Standards of Practice Committee participated through four rounds of the Delphi to reach consensus as reported.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

The draft document is critically reviewed by Standards of Practice Committee members, either by telephone conference calling or face-to-face meeting. The finalized draft from the Committee is sent to the Society of Interventional Radiology (SIR) membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee and appropriate revisions made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate periprocedural management of coagulation status and hemostasis risk in percutaneous image-guided interventions

Potential Harms

- Protamine's half-life is short and ranges from 5 to 7.5 minutes, which can lead to "paradoxical" re-anticoagulation after protamine administration. Side effects of protamine include hypotension, bradycardia, pulmonary arterial hypertension, decreased oxygen consumption, and anaphylactoid reactions.
- Intravenous administration of vitamin K is associated with a risk of anaphylactoid reaction. The U.S. Food and Drug Administration has issued a "black box" warning for the subcutaneous, intravenous, and intramuscular routes of administration due to reports of severe reactions, including fatalities.
- The use of fresh frozen plasma (FFP) in nonbleeding cases before image-guided interventions must be weighed against the potential risks of transfusion. An increasingly recognized and often life-threatening complication, transfusion-related acute lung injury, has an insidious onset characterized by hypoxia, dyspnea, and volume overload, occurring after transfusion of approximately 1 in 8,000–60,000 U of FFP. The ability of patients with congestive heart failure or other similar conditions to handle the volume and rate at which transfusions may occur are limited and should be addressed accordingly. Other important transfusion-related complications include allergic or anaphylactic reactions, transmittal of infectious diseases including human immunodeficiency virus (HIV), hepatitis B, and hepatitis C, albeit rarely, and acute hemolysis secondary to anti-A or anti-B antibodies.
- Similar to the plasma-rich product FFP, platelets are also associated with a multitude of risks, including transfusion-related acute lung injury, anaphylaxis, and viral/bacterial contamination. One study reported that, with increasing number of platelet transfusions, the effectiveness progressively decreased, even when lymphocytotoxic antibody-positive patients were removed from the analysis. The judicious use of platelet transfusion may reduce the overall benefit in a time of need, such as in the setting of active bleeding.
- Refer to the "Efficacy and Complications" section of the original guideline document for a discussion of bleeding complications, including life-threatening or fatal bleeding, with antiplatelet therapy in image-guided procedures.

Qualifying Statements

Qualifying Statements

- Although it is likely that individual practice parameters will vary from this document, each practitioner should monitor outcomes and look for trends, both positive and negative, which may suggest modifications or adjustments to these parameters. Outlining bleeding complication rates for specific procedures is beyond the scope of this document and, in many cases, may be difficult or impossible to accurately accomplish because of the lack of high-level data. Where external benchmarks are not available, practitioners may choose to benchmark against their own historical data as part of an overall quality improvement program.
- The clinical practice guidelines of the Society of Interventional Radiology (SIR) attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances

relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2009 Jul (revised 2012 Jun)

Guideline Developer(s)

Society of Interventional Radiology - Medical Specialty Society

Source(s) of Funding

Society of Interventional Radiology

Guideline Committee

Society of Interventional Radiology Standards of Practice Committee

Composition of Group That Authored the Guideline

Committee Members: Indravadan J. Patel, MD, Department of Radiology, University Hospitals Case Medical Center, Cleveland, Ohio; Jon C. Davidson, MD, Department of Radiology, University Hospitals Case Medical Center, Cleveland, Ohio; Boris Nikolic, MD, MBA, Department of Radiology, Albert Einstein Medical Center, Philadelphia, Pennsylvania; Gloria M. Salazar, MD, Department of Radiology, Massachusetts General Hospital, Boston, Massachusetts; Marc S. Schwartzberg, MD, Radiology Associates of Central Florida, Leesburg, Florida; T. Gregory Walker, MD, Section of Cardiovascular Imaging and Intervention, Massachusetts General Hospital, Boston, Massachusetts; Wael A. Saad, MD, Department of Radiology, University of Virginia Health System, Charlottesville, Virginia

Financial Disclosures/Conflicts of Interest

None of the authors have identified a conflict of interest.

Guideline Endorser(s)

Cardiovascular and Interventional Radiological Society of Europe - Nonprofit Organization

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Malloy PC, Grassi CJ, Kundu S, Gervais DA, Miller DL, Osnis RB, Postoak DW, Rajan DK, Sacks D, Schwartzberg MS, Zuckerman DA, Cardella JF, Standards of Practice Committee with Cardiovascular and Interventional [trunc]. Consensus guidelines for periprocedural management of coagulation status and hemostasis risk in percutaneous image-guided interventions. J Vasc Interv Radiol. 2009 Jul;20(7 Suppl):S240-9. [56 references]

Guideline Availability

Electronic copies: Available from the [Society of Interventional Radiology Web site](#) .

Print copies: Available from the Society of Interventional Radiology, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on August 19, 2011. The information was verified by the guideline developer on September 8, 2011. This summary was updated by ECRI Institute on March 10, 2014 following the U.S. Food and Drug Administration advisory on Low Molecular Weight Heparins. This summary was updated by ECRI Institute on January 23, 2015.

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